Longstanding Exercise Therapy in Patients with Rheumatoid Arthritis

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19895

Bron
NTR

Verkorte titel
L-EXTRA study

Aandoening

Rheumatoid Artritis

Ondersteuning

Primaire sponsor: Leiden University Medical Centre, LUMC
Overige ondersteuning: Ministry of Health, Welfare and Sport and ReumaNederland and Koninklijk Nederlands Genootschap voor Fysiotherapie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure of effectiveness is the individual level of functioning (activities

and participation), as measured with the Patient-Specific Complaints instrument (PSC) at 52 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Rheumatoid arthritis (RA) is a chronic systemic disease, mainly characterized by arthritis of the peripheral joints, affecting about 0.4-1% of the population, with women being more often affected than men. During the course of their disease, most patients use short, intermittent physical therapy treatment (active exercise therapy) in order to prevent or diminish limitations in activities or participation. However, there is a substantial subgroup of patients with RA (< 5%) with joint damage or persistent high disease activity, complications of the disease or its treatment or comorbidity, resulting in complex limitations in activities and participation. Due to the individual nature of the problems and resulting disability, in this group the exercise therapy treatment is currently highly personalized and usually longstanding (i.e. longer than 12 weeks and more than 20 sessions per year). Only one high quality randomized controlled trial proved the effectiveness and safety of longstanding exercise therapy, however this concerned a selected group of patients with stable RA and little joint damage (De Jong 2003, 2004). Research on effectiveness of longstanding exercise therapy in the abovementioned patient group with complex limitations in activities and participation is absent.

Objectives:
This study aims to underpin the delivery of longstanding exercise therapy in the subgroup of patients with RA and complex disability.
There are 3 research questions to be addressed:
1. Is longstanding, optimized active exercise therapy more effective with respect to functional ability than usual care in patients with RA with severe functional disability over a period of 52 weeks?
2. Which option (longstanding, optimized active exercise therapy or usual care) is more cost-effective?
3. What is the long-term course of functional ability, health status and health care consumption of patients using longstanding, optimized active exercise therapy?

Study design:
Randomized, controlled trial comparing longstanding, active exercise therapy with usual care (1:1). After the experimental period of 52 weeks at which the primary end-point is assessed, the intervention will be continued in the intervention group. Effects will be monitored at follow-up measurements after 104 weeks and after 156 and 208 weeks or at the end of the study, depending on date of inclusion. At 52 weeks, the intervention will also be offered to the patients allocated to the usual care group.

Study population:
215 patients with a confirmed diagnosis of RA, with persistent high disease activity, joint damage, complications of the disease or its treatment or comorbidity, resulting in complex limitations in activities and participation.

Intervention and control conditions:
The intervention concerns longstanding, intensive active exercise therapy (52 weeks), aimed at the improvement of specific individual limitations in daily activities and participation. It consists of a standardized program comprising active modalities (functional exercises, aerobic exercises, muscle strengthening and flexibility/joint range of motion exercises), with the type of exercises, their intensity, frequency, duration, site of delivery (practice or at home) and progression being tailored to the individual patients' functional disability and ensuing needs and goals. The control condition consists of care as usual, left to the discretion of the treating physicians and the patients.

Main study parameters/endpoints:
Assessments are done at 0, 12, 26, 52, 104, and 156 and 208 weeks or end of the study (48 months). The primary outcome measure of effectiveness is the individual level of functioning (activities and participation), as measured with the Patient-Specific Complaints instrument (PSC) at 52 weeks.
Secondary outcome measures include the 10-item Patient Reported Outcomes Measurement Information System (PROMIS), the Health Assessment Questionnaire-Disability Index (HAQ-DI) and a 6 minute walk test for functional ability; and he RAQol and SF-36 for health related Quality of life. In order to address the topic of cost-effectiveness, the EuroQol (EQ-5D-5L) for health valuation and comprehensive measurements of costs for an economic analysis will be administered as well.
Apart from the primary and secondary outcome measures, sociodemographic and disease characteristics, will be recorded. The presence of comorbidity will be recorded by means of the comorbidity questionnaire developed by the Dutch Central Bureau of Statistics.
In addition, an anchor question regarding the perceived effectiveness will be added in all cases where longstanding exercise therapy was used (intervention and control group if starting after 52 weeks) ("has the exercise therapy changed your daily functioning"), as well as a short questionnaire on patient satisfaction with treatment. Furthermore, we will evaluate the content of care provided and the compliance of the pa-tients in the intervention group by asking the patients to fill out a registration form on the frequency, duration, and content of treatment. In a random sample of 10% we will validate the registration form with the records of the physical therapist (content, duration). The perception of any side effects of exercise therapy will be recorded. If treatment is discontinued, the reasons will be recorded.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The intervention concerns exercise therapy delivered by trained primary care physical therapists according to a standardized protocol, with no extra risks as compared to the regular delivery of primary care exercise therapy. Regarding the burden, the assessments mainly consist of the completion of questionnaires at home (max. 1 hour) and a site visit with one performance test (6-minute walk test) and the answering of a number of questions (max. total visit duration ½ hour). The maximum number of site visits is 5 (1 screening and

maximum 4 evaluation visits at: baseline, 26 weeks, 52 weeks (primary endpoint) and 104 weeks. Evaluations at 156 and 208 weeks/end of study only consist of questionnaires.

Doel van het onderzoek

This study aims to underpin the delivery of longstanding exercise therapy in the subgroup of patients with RA and complex disability.
There are 3 research questions to be addressed:
1. Is longstanding, optimized active exercise therapy more effective with respect to functional ability than usual care in patients with RA with severe functional disability over a period of 52 weeks?
2. Which option (longstanding, optimized active exercise therapy or usual care) is more cost-effective?
3. What is the long-term course of functional ability, health status and health care consumption of patients using longstanding, optimized active exercise therapy?

Onderzoeksopzet

Assessments are done at 0, 12, 26, 52, 104, and 156 and 208 weeks or end of the study (48 months). The primary outcome measure of effectiveness is the individual level of functioning (activities and participation), as measured with the Patient-Specific Complaints instrument (PSC) at 52 weeks.

Onderzoeksproduct en/of interventie

Longstanding optimized active exercise therapy (intervention) or usual care (control)

Contactpersonen

Publiek

LUMC, Leiden
Thea Vliet Vlieland

071-5263613

Wetenschappelijk

LUMC, Leiden
Thea Vliet Vlieland

071-5263613

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A confirmed diagnosis of RA, with persistent high disease activity, joint damage, complications of the disease or its treatment or comorbidity, resulting in complex limitations in activities and participation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Recent (<3 months) or present individual physiotherapy or exercise therapy or multidisciplinairy rehabilitation treatment

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	215
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52885
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8235
CCMO	NL69866.058.19
OMON	NL-OMON52885

Resultaten